

REMARKS

Claims 1-17 and 20-24 were pending in the instant application as of the issuance of the Office Action mailed on December 8, 2005. By the current Amendment to Claims, claims 1-8, 10-12, 15, 17, 20 and 22 have been amended, claims 21 and 23-24 have been cancelled and claims 25 and 26 have been added.

Claims 1-8, 10-12, 15, 17, 20 and 22 have been amended merely to attend to formalities, for example, to attend to grammatical formalities. Claims 25 and 26 have been added to cover particular embodiments of the invention. Support for new claim 25 can be found throughout the specification, for example, on page 14, lines 27-31. Support for new claim 26 can be found throughout the specification, for example, on page 22, line 22 to page 23, line 4. No new matter has been added by the foregoing amendments and introduction of new claims.

Claims 21 and 23-24 have been cancelled without prejudice to their inclusion in this or a subsequently filed application.

Applicants respectfully request that the aforementioned amendments be entered. Applicants note that the foregoing amendments have been made in order to expedite examination and in no way should be construed as acquiescence to the validity of the rejections set forth in the Office Action. Following entry of the foregoing amendments, claims 1-8, 9-14, 15-17, 20, 22, 25 and 26 will be pending.

Restriction Requirement

Claims 1-17 and 20-24 are subject to a restriction requirement. The Examiner has required restriction between the following inventions in the above-identified application:

- Group I: Claims 1-4, 6-8 and 12, as specifically drawn to the special technical feature of a polynucleotide;
- Group II: Claims 5 and 13, as specifically drawn to the special technical feature of a polypeptide;
- Group III: Claims 9 and 14, as specifically drawn to the special technical feature of an antibody;

- Group IV: Claim 10, as specifically drawn to the special technical feature of a method of detecting the presence or absence of a polynucleotide in a biological sample;
- Group V: Claim 11, as specifically drawn to the special technical feature of a method of detecting a polypeptide in a biological sample;
- Group VI: Claim 15, as specifically drawn to the special technical feature of a method of treating a tumor comprising administering an effective amount of a polynucleotide;
- Group VII: Claim 16, as specifically drawn to the special technical feature of a method of treating a tumor comprising administering an effective amount of a polypeptide;
- Group VIII: Claim 17, as specifically drawn to the special technical feature of a method of treating a tumor comprising administering an effective amount of an antibody;
- Group IX: Claims 20 and 23-24, as specifically drawn to the special technical feature of a method for identifying a substance capable of binding to an orbit polypeptide; and
- Group X: Claims 21 and 22, as specifically drawn to a substance capable of binding to an orbit polypeptide.

In response to the Restriction Requirement set forth in the Office Action mailed on December 8, 2005, Applicants hereby elect, *with traverse*, to prosecute the claims of Group I (Claims 1-4, 6-8 and 12, as specifically drawn to the special technical feature of a polynucleotide). Applicant's election of the foregoing subject matter is without prejudice to Applicants' rights to pursue non-elected subject matter in other applications.

In part, Applicants traverse the Restriction Requirement as a whole on the ground that the requirement itself is in conflict with the finding of a unity of invention during the international stage. Indeed, Applicants point out that no objection as to lack of unity of invention was raised during the international phase of International Application No. PCT/GB96/02662, of which this case is a 35 U.S.C. § 371 national phase application (see International Search Report and

International Preliminary Examination Report for PCT/GB96/02662, attached herewith as Appendices A and B, respectively). PCT Article 27 provides that it is improper for national offices to require compliance with the requirements relating to the form or contents of the application different from or additional to those which are provided for in the PCT. Moreover, MPEP § 1850 states that

...when the Office considers international applications as an International Searching Authority, as an International Examining Authority, and *during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111.* (emphasis added)

Indeed, the same standard for unity of invention is applicable to both international applications and national phase applications. Accordingly, the present lack of unity of invention rejection during the national phase is in conflict with the finding of a unity of invention during the international stage and should be withdrawn.

Furthermore, Applicants submit that, minimally, Groups I and II form a single general inventive concept and thereby possess unity of invention. Applicants direct the Examiner's attention to the WIPO "PCT International Search and Preliminary Examination Guidelines" (2004). Specifically, Example 39 (see Chapter 10.59) provides the following example:

Claim 1: Isolated protein X having SEQ ID NO:1.

Claim 2: Isolated DNA molecule encoding protein X of claim 1...

The claimed DNA molecule encodes protein X, and therefore protein X and the DNA encoding protein X share a corresponding technical feature. Consequently, the claims have unity of invention (*a priori*)... Because protein X makes a contribution over the prior art, protein X and the DNA encoding protein X share a special technical feature.

Indeed, both Groups I and II are directed to nucleotide and polypeptide sequences, respectively, encoding the orbit protein and, accordingly, share the same special technical feature (*i.e.*, the identification and sequencing of the orbit protein). Indeed, the nucleotide and polypeptide sequences are intimately related in light of the genetic code. Accordingly, Applicants submit that in accordance with PCT Rule 13.1, as evidenced by the WIPO Guidelines, at least Groups I and II possess unity of invention and, minimally, these two groups should be rejoined for the purpose of initial examination.

In addition, Applicants submit that the U.S. Patent Office has already indicated that the search of multiple sequences is acceptable. Applicants direct the Examiner's attention to

M.P.E.P. § 1850 “Unity of Invention – Nucleotide Sequences” which states that “the Commissioner has decided *sua sponte* to partially waive 37 CFR 1.475 and 1.499 *et seq.* to permit applicants to claim up to ten (10) nucleotide sequences that do not have the same or corresponding technical feature.” Accordingly, Applicants submit that while Groups I and II are directed to a nucleotide and amino acid sequence, respectively, examination of two sequences in the same application would be appropriate and within the spirit of M.P.E.P. § 1850.

For each of the foregoing reasons, Applicants respectfully request withdrawal of the Restriction Requirement as applied to all of the pending claims, or at least rejoinder of Groups I and II. In addition, Applicants assert that the traversal of the Restriction Requirement is without prejudice to the Applicants’ right to traverse a further Restriction Requirement raised in this or a subsequently filed application.

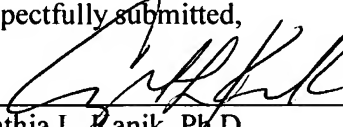
Further, if the Restriction Requirement is maintained as it pertains to the presently withdrawn method claims, it is Applicants’ understanding that once a composition claim is found to be allowable, the pending method claims that depend from or otherwise include all the limitations of an allowable composition claim will be rejoined in accordance with the provisions of MPEP § 821.04.

SUMMARY

Applicants respectfully submit that the above-identified application is in condition for allowance. If a telephone conversation with Applicants’ attorney would expedite prosecution of the above-identified application, the Examiner is urged to call Applicants’ Attorney at (617) 227-7400.

Dated: February 28, 2006

Respectfully submitted,

By 

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INTERNATIONAL SEARCH REPORT

APPENDIX A

Intern 1al Application No

PCT/GB 00/02662

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/12 C07K14/435 C07K16/18 C12Q1/68 G01N33/50
A61K38/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12N C07K C12Q G01N A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

BIOSIS, STRAND

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	INOUE YOSHIHIRO H ET AL: "Orbit, a novel microtubule-associated protein essential for mitosis in <i>Drosophila melanogaster</i> ." JOURNAL OF CELL BIOLOGY, vol. 149, no. 1, 3 April 2000 (2000-04-03), pages 153-165, XP000952651 ISSN: 0021-9525 page 154 -page 155; figures 6,7 --- -/--	1-11

☒ Further documents are listed in the continuation of box C.☐ Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

6 November 2000

Date of mailing of the international search report

15/11/2000

Name and mailing address of the ISA

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Authorized officer

Espen, J

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
T	<p>LEMOS CATARINA L ET AL: "Mast, a conserved microtubule-associated protein required for bipolar mitotic spindle organization." EMBO (EUROPEAN MOLECULAR BIOLOGY ORGANIZATION) JOURNAL, vol. 19, no. 14, 17 July 2000 (2000-07-17), pages 3668-3682, XP000952720 ISSN: 0261-4189</p>	
A	<p>DO CARMO AVIDES MARIA ET AL: "Abnormal spindle protein, Asp, and the integrity of mitotic centrosomal microtubule organizing centers." SCIENCE (WASHINGTON D C), vol. 283, no. 5408, 12 March 1999 (1999-03-12), pages 1733-1735, XP000952645 ISSN: 0036-8075</p>	
X	<p>DATABASE PIR 'Online! KIAA0627, ACCESSION NUMBER T00386, 1 February 1999 (1999-02-01) ISHIKAWA K. ET AL: "Prediction of the coding sequences of unidentified human genes" XP002150920 cited in the application Sequence</p>	1,2,5
X	<p>DATABASE PIR 'Online! ENTRY KIAA0622, ACCESSION NUMBER T00387, 1 February 1999 (1999-02-01) ISHIKAWA . ETAL.: "Prediction of the coding sequences of unidentified human genes" XP002150921 cited in the application Sequence</p>	1,2,5

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 21-24

Present claims 21-24 relate to a substance defined by reference to a desirable characteristic or property, namely binding to an orbit polypeptide or a homologue, derivative, variant or fragment thereof.

The claims cover all substances having this characteristic or property, whereas the application provides no support within the meaning of Article 6 PCT and/or no disclosure within the meaning of Article 5 PCT. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the substance by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search impossible.

Consequently, no search has been carried out for said claims.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

PATENT COOPERATION TREATY

Appendix B

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P006774WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/02662	International filing date (day/month/year) 11/07/2000	Priority date (day/month/year) 13/07/1999
International Patent Classification (IPC) or national classification and IPC C12N15/12		
Applicant UNIVERSITY OF DUNDEE et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 6 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☒ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☐ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 02/02/2001	Date of completion of this report 13.09.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Seranski, P Telephone No. +49 89 2399 7846 <div data-bbox="1339 1816 1518 1974" data-label="Image"> </div>

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/02662

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-67 as originally filed

Claims, No.:

1-24 as originally filed

Drawings, sheets:

1-11 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/02662

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

☐ copy of the earlier application whose priority has been claimed.

☐ translation of the earlier application whose priority has been claimed.

2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.

Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:
see separate sheet

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☒ the entire international application.

☐ claims Nos. .

because:

☒ the said international application, or the said claims Nos. 15-17 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-14, 18-20 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/02662

could be formed.

☒ no international search report has been established for the said claims Nos. 21-24.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

1. Re Item II

Priority

The priority document pertaining to the present application was not available at the time of establishing this opinion. Hence, it is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. If it later turns out that this is not correct, the P document cited in the International Search Report becomes relevant to assess whether all claims satisfy the criteria set forth in Article 33(1) PCT.

2. Re Item III

Non establishment of Opinion

2.1 Claims 21-24 have not been searched by the International Search Authority for reasons given in the International Search Report. Therefore, no opinion relating to claims 21-24 has been drawn by the Examining Authority (Rule 66.1(e) PCT).

2.2 Claims 1 and 2 could not be examined because of the unclear formulation of the subject matter for which protection is sought. The designation of the gene name 'orbit' is an arbitrary designation by the inventor which does not have a clear art-recognized meaning. The term "homologue" is also completely unclear.

2.3 The polynucleotide of claim 3(b) and (c) is not clearly defined by the definition that it is 'capable of hybridising' to the nucleotide sequence set out in Seq ID N°1. Depending on the hybridisation conditions, almost every polynucleotide can hybridise to said sequence. In consequence, claim 3(d) lacks also clarity because it refers to claims 3 (b) and (c). Therefore, the subject matter for which protection is sought is not clearly defined and no opinion could be drawn concerning novelty, inventive step and industrial applicability of claims 3 and 4.

2.4 Also claim 5 lacks clarity as it relates to homologs, variants, derivatives and fragment of the disclosed polypeptide sequence. Thus the examination had to be limited to the polypeptide with SeqID N°2.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/02662

2.5 The examination of claims 4-13 and 14, when interpreted as referring to claim 9 instead of claim 10, was limited to the disclosed nucleotide sequence with SeqID N°1 and the polypeptide with SeqID N°2.

2.6 Because claims 18-20 again relate to unclear subject matter as set out under 2.2 and 2.4, no opinion was drawn regarding these claims.

2.7 For the assessment of the present claims 15-17 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

4. Re Item VIII

Clarity (Art. 6 PCT)

4.1 Page 65, lines 4-11 contain formulations that are not clear under the current practice of the Examining Authority.

4.2 Claim 14 contains a reference to the wrong claim, rendering the claim unclear.